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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/777,451      | 02/12/2004  | Lilip Lau            | PARCR 67465         | 4778             |

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EXAMINER

ALTER, ALYSSA M

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/777,451

Applicant(s)

LAU ET AL.

Examiner

Alyssa M. Alter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 65-101 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 65-101 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/19/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 65-101 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 65-144 of copending Application No. 10/793,546 (US Patent Publication 20050102012 A1).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a cardiac harness for the heart with at least one electrode.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 65-101 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of copending Application No. 10/704,376 (US Patent Publication 20050102010 A1).

Although the conflicting claims are not identical, they are not patentably distinct from

each other because they both claim a cardiac harness for the heart with at least one electrode connected to a power source for supplying the electrode.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 65-101 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 65-90 of copending Application No. 11/002,609 (US Patent Publication 20050119717 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a cardiac apparatus that is positioned on the hearts exterior with at least one electrode.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 65-101 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 11/051,823. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a cardiac harness for the heart with at least one electrode connected to a power source to be delivered minimally invasively.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. Claims 68, 77, 90 and 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 68, 77, 90 and 96 recite the limitation "minimally invasively". The examiner is unsure of how the cardiac harness is delivered minimally invasively and what that Applicant defines as minimally.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 65-101 are rejected under 35 U.S.C. 102(b) as being anticipated by Alferness et al. (US 6,169,922). Alferness et al. discloses a defibrillating cardiac jacket with interwoven electrode conductors connected to a power source.

As to claims 65, 74 and 83-84, "In one undulating pattern, the electrode conductors 101 are woven into alternating ones of the strands 21a, 21b. For example, an electrode conductor 101 may be woven into strand 21b for a distance equal to the length of two cells 23. Then, the electrode conductor 101 is woven into strand 21a for a distance equal to the length of two cells 23. This creates a zigzag pattern repeated along the length of the electrode conductor 101"(col. 9, lines 43-50). Therefore, the undulating stands or rows are the electrodes and thus the conductive portion.

As to claims 66-67, 75-76 and 85-86, "the fibers 21a, 21b of the jacket material 18 may be selectively metalized with such fibers serving as the electrode conductors"(col. 10, lines 19-21). "The strands 21a, 21b define a grid of open cells 23. Uninsulated, electrically conductive electrode conductors 101 are interwoven through the cells 23. Examples of such electrode conductors 101 include titanium wire and platinum-coated stainless steel. Such electrode conductors 101 may be braided, multi-strand wires"(col. 9, lines 36-42).

As to claims 93-95, according to Merriam-Webster, "spring is an elastic body or device that recovers its original shape when released after being distorted" {please see Reference V}. Since the jacket is constructed from "flexible material" (col. 3, line 47) that is temporarily stretched for placement over the heart, the examiner considers the flexible material of the jacket to have elements of a spring. Some of these flexible spring-like fibers have metal interwoven to create electrodes.

As to claims 68, 77, 90 and 96, the harness is implicitly configured to be delivered minimally invasively in accordance with modern surgical procedures.

As to claims 69, 78, 91 and 97, since the jacket material is dielectric and the electrodes are interweaved with the dielectric jacket fibers to form undulating strands or rows, there are portions without undulating strands or rows interweaved. These portions are the electrically insulated portions, and thus separate the undulating strands or rows.

As to claims 70, 79, 92 and 98, according to Merriam-Webster, "dielectric is a nonconductor of direct electric current"{please see Reference U}, thus being insulative. "The knit material is an electrical insulator" (col. 8, lines 46-47) and "the fibers are 70

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Denier polyester. While polyester is presently preferred, other suitable materials include polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE) or polypropylene”(col. 8, lines 30-33). “Further, an anti-fibrosis lining (such as a PTFE coating on the fibers of the knit) could be placed between the heart H and the jacket 10. Alternatively, the fibers 20 can be coated with PTFE”(col. 9, lines 11-14).

As to claims 71-73, 80-82, 87-89 and 99-101, since Alferness et al. utilizes electrodes disposed on a harness to sense the heart and dispense electrical energy, the examiner considers the electrodes to be implicitly capable of being used in pacing therapy. Therefore, the defibrillation electrodes on the cardiac harness are capable of being used for pacing the heart. Also, “in defibrillators, the electrode conductors also act to receive signals from the heart. Since the electrode conductors are in close proximity to the heart, these electrode conductors permit easy detection of cardiac signals by the implantable defibrillator 106 facilitating analysis of electrical activity of the heart”(col. 10, lines 10-15).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

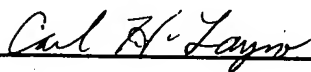
1. Cox et al. (US 6,730,016) discloses a cardiac disease treatment and device.
2. Knisley (US 5,824,028) discloses a line electrode oriented relative to fiber direction.
3. Heilman et al. (US 5,558,617) discloses a cardiac compression band-stay-pad assembly and method of replacing the same.
4. Lau et al. (US 6,612,978) discloses an expandable cardiac harness for treating congestive heart failure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CARL LAYNO  
PRIMARY EXAMINER



Alyssa M Alter  
Examiner  
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